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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,574	05/26/2005	Martin Alan Lee	41577/316310	9930

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JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER

RAMDHANIE, BOBBY

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,574

Applicant(s)

LEE ET AL.

Examiner

BOBBY RAMDHANIE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/24/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pourahmadi et al (WO99/33559). Regarding Claim 1, Pourahmadi et al teaches an apparatus for processing a fluid sample comprising: (i) A sample processing chamber comprising a fluid inlet and a fluid outlet (Abstract & Figure 6 Items 28 and 30; (ii) A waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path (Abstract and Figure 16 Item 203); at least (iii) Two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet (Figure 2); (iv) A means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path (Page 6 lines 30-36); and (v) A passive means for restricting the flow of fluid (Page 6 lines 30-36).

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3. For Claim 2, Pourahmadi et al teaches an apparatus according to Claim 1 wherein the means for moving fluid from at least one of the at least two further chambers through the sample processing chamber comprises a means for generating a vacuum (Page 6 lines 30-36).

4. For Claim 3, Pourahmadi et al teaches an apparatus according to Claim 2 wherein the waste chamber comprises an outlet port which is connected to the means for generating a vacuum (Page 30 lines 11-14).

5. For Claim 4, Pourahmadi et al teaches an apparatus according to Claim 2 wherein the analyte flow path comprises an outlet port which is connected to the means for generating a vacuum (Page 30 lines 11-14).

6. For Claim 6, Pourahmadi et al teaches an apparatus according to Claim 5 wherein the means for moving fluid from at least one of the two further chambers through the sample processing chamber additionally comprises a means for generating a vacuum (Page 30 lines 11-14).

7. For Claim 7, Pourahmadi et al teaches an apparatus according to Claim 1, wherein the means for moving fluid from each of the two further chambers through the sample processing chamber moves the fluid sequentially from the first at least two further chambers through the sample processing chamber and into the waste chamber and then from the second at least two further chambers through the sample processing chamber and into either the waste chamber or the divergent analyte flow path (Figure 2). Examiner takes the position that the apparatus is taught by Pourahmadi et al. This product by process claim, as a result is anticipated by Pourahmadi et al.

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8. For Claim 8, Pourahmadi et al teaches an apparatus according to Claim 1 wherein the passive means for restricting the flow of fluid comprises a valve located in the fluid communication between the sample processing chamber and the waste chamber (Page 5 lines 4-17).

9. For Claim 9, Pourahmadi et al teaches an apparatus according to Claim 8 wherein the valve is down stream of the divergent analyte flow path (Page 5 lines 4-17).

10. For Claim 10, Pourahmadi et al teaches an apparatus according to Claim 8 wherein the valve comprises a bead which is opened by applying a positive or negative pressure (Page 5 lines 4-17). Examiner takes the position that fluid diodes comprise balls or beads which can be used to shut off fluid flow in one direction when positive or negative pressure is applied.

11. For Claim 11, Pourahmadi et al teaches an apparatus according to Claim 1 wherein the passive means for restricting the flow of fluid comprises a reservoir located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber (Figure 2).

12. For Claim 12, Pourahmadi et al teaches an apparatus according to Claim 1 wherein the passive means for restricting the flow of fluid comprises a fluid pathway of small diameter such that fluid can not flow through the pathway without the application of a positive or negative pressure, located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber (Page 28 line 36 to Page 29 line 22).

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13. For Claim 13, Pourahmadi et al teaches an apparatus according to Claim 1, comprising a collection chamber downstream of the analyte flow path and in fluid communication with the analyte flow path outlet (Page 5 lines 15-17).

14. For Claim 14, Pourahmadi et al teaches an apparatus according to Claim 13 wherein the collection chamber comprises a reagent, preferably a reagent comprising one or more nucleic acid amplification reagents, more preferably a reagent selected from the group consisting of nucleic acid primers, nucleic acid probes, fluorescing dyes, enzyme buffers, nucleotides, magnesium salts, bovine serum albumen, and denaturants (Page 19 line 35 to Page 20 line 7).

15. For Claim 15, Pourahmadi et al teaches an apparatus according to Claim 13 wherein collection chamber comprises an outlet port which optionally may be connected to a means for generating a vacuum (Page 20 lines 7-9).

16. For Claim 16, Pourahmadi et al teaches an apparatus according to Claim 15 wherein the apparatus comprises a post processing chamber down stream from the collection chamber in fluid communication with the collection chamber outlet and which optionally itself comprises an outlet which may be connected to a means for generating a vacuum (Figure 2).

17. For Claim 17, Pourahmadi et al teaches an apparatus according to Claim 1, wherein the sample processing chamber comprises an active member, preferably a trapping member selected from the group consisting of a microfluidic chip, a solid phase material, a filter, a filter stack, an affinity matrix, a magnetic separation matrix,

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a size exclusion column, a capillary tube, and mixtures thereof (Page 27 line 30 to Page 28 line 5 or Page 11 lines 12-18).

18. For Claim 18, Pourahmadi et al teaches an apparatus according to Claim 17 wherein the sample processing chamber comprises a glass fiber filter membrane (Page 27 line 30 to Page 28 line 5 or Page 11 lines 12-18).

19. For Claim 19, Pourahmadi et al teaches an apparatus according to Claim 1 wherein at least one of the at least two further chambers is pre-filled with a buffer solution, preferably a buffer solution selected from the group consisting of an aqueous solution of potassium acetate and Tris.hydrochloride, or an aqueous ethanolic solution of potassium acetate and Tris.hydrochloride (Page 18 lines 6-20).

20. For Claim 20, Pourahmadi et al teaches an apparatus according to Claim 1 wherein at least one of the at least two further chambers acts as a sample chamber comprising an inlet port through which a sample is introduced into the apparatus (Figure 2 Item 103).

21. For Claim 21, Pourahmadi et al teaches an apparatus according to Claim 20 wherein the sample chamber inlet port comprises a filter membrane (Page 30 lines 11-18).

22. For Claim 22, Pourahmadi et al teaches an apparatus according to Claim 20 wherein the sample chamber comprises a reagent, preferably a reagent comprising a lysis reagent, more preferably a chaotrophic salt (Page 18 lines 6-20 & Page 23 line 26 to Page 24 line 3).

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23. For Claim 23, Pourahmadi et al teaches an apparatus according to Claim 1, wherein the apparatus comprises at least one chamber located externally to the main body of the apparatus (Page 5 lines 14-17).

24. For Claim 24, Pourahmadi et al teaches an apparatus according to Claim 23 wherein the chamber located externally to the main body of the apparatus is the collection chamber (Page 5 lines 14-17).

25. For Claim 25, Pourahmadi et al teaches an apparatus according to Claim 23 wherein the chamber located externally to the main body of the apparatus is at least one of the at least two further chambers (Page 5 lines 14-17).

26. For Claim 27, Pourahmadi et al teaches a method of processing a fluid sample comprising: (i) Placing the sample in the sample processing chamber of an apparatus according to Claim 1 (Abstract & Figure 2); (ii) Applying a positive or negative pressure to move fluid through the apparatus (Page 6 lines 30-36); (iii) subjecting the sample to one or more processing steps (Page 19 line 35 to Page 20 line 7); and (iv) collecting the processed sample from the divergent analyte flow path (Figure 2 & (Page 5 lines 14-17).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 5 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al. Regarding Claim 5, Pourahmadi et al teaches an apparatus according to Claim 1. Pourahmadi et al does not teach that the means for moving fluid from at least one of the at least two further chambers through the sample processing chamber comprises a plunger capable of being depressed to expel fluid from the at least one further chamber. Pourahmadi et al does however teach fluid motive sources such as one or more pumps, vacuums, or pressure sources (Page 6 lines 30-34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pourahmadi et al with a plunger because this would be a fluid motive source that would be adequate to move the fluid through the cartridge.

4. For Claim 26, Pourahmadi et al teaches an apparatus according to Claim 23. Pourahmadi et al further teaches that at least one chamber is located externally. Pourahmadi et al does not teach that the walls which are coated with an electrically conducting polymer. Pourahmadi et al does teach that other sample chamber(s) may be coated with a silicon oxide or a metal film to act as a heater. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the walls

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of the external chamber to be lined with a electrically conductive polymer because it is known in the art of lysing bacterial cultures, biological cells, or yeast that a temperature drop of a digestion can degrade desired genes and proteins that have been expressed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28 & 29 provide for the use of the apparatus of Claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 28 & 29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Ramdhanie, Ph.D./
Examiner, Art Unit 1797
BR

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797